

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Jian-Yun DONG *et al.*

Serial No.: 10/555,109

Filed: November 1, 2005

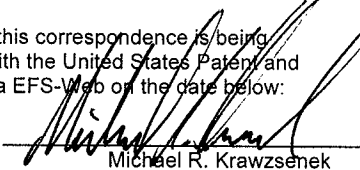
For: AN AUTOLOGOUS UPREGULATION  
MECHANISM ALLOWING OPTIMIZED  
CELL TYPE-SPECIFIC AND  
REGULATED GENE EXPRESSION  
CELLS

Group Art Unit: 1636

Examiner: Unknown

Atty. Dkt. No.: MESC:014US

Confirmation No.: 5410

CERTIFICATE OF ELECTRONIC TRANSMISSION	
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May 25, 2007	
Date	Michael R. Krawczanek

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

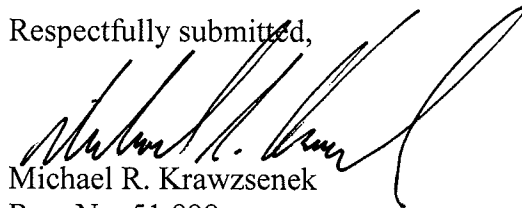
In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/MESC:014US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Date: May 25, 2007

Form PTO-1449 (modified)	Atty. Docket No.: MESC:014US	Serial No.: 10/555,109
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)	Applicant: Jian-Yun DONG <i>et al.</i>	
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U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>

### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language
	B1	WO 01/30799	05/03/01	WIPO	English

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	C1	Almendo <i>et al.</i> , "Cloning of the human platelet endothelial cell adhesion molecule-1 promoter and its tissue-specific expression," <i>J. Immunol.</i> , 157:5411-5421, 1996.
	C2	Andriani <i>et al.</i> , "Use of the probasin promoter ARR <sub>2</sub> PB to express Bax in androgen receptor-positive prostate cancer cells," <i>J. Natl. Cancer Inst.</i> , 93:1314-1324, 2001.
	C3	Barnes <i>et al.</i> , "Cloning of cardiac, kidney, and brain promoters of the feline <i>nex1</i> gene," <i>J. Biol. Chem.</i> , 272:11510-11517, 1997.
	C4	Belousova <i>et al.</i> , "Modulation of adenovirus vector tropism via incorporation of polypeptide ligands into the fiber protein," <i>J. Virol.</i> , 76:8621-8631, 2002.
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	C8	Buskens <i>et al.</i> , "A genetically retargeted adenoviral vector enhances viral transduction in esophageal carcinoma cell lines and primary cultured esophageal resection specimens," <i>Ann. Surg.</i> , 238:815-824, 2003.

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	C11	Dahm <i>et al.</i> , "A longitudinal assessment of bowel related symptoms and fecal incontinence following radical perineal prostatectomy," <i>J. Urol.</i> , 169:2220-2224, 2003.
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	C41	Kanai, "Transcriptional targeted gene therapy for hepatocellular carcinoma by adenovirus vector," <i>Mol. Biotechnol.</i> , 18:243-250, 2001.
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	C45	Kijima <i>et al.</i> , "Application of the Cre recombinase/ <i>loxP</i> system further enhances antitumor effects in cell type-specific gene therapy against carcinoembryonic antigen-producing cancer," <i>Cancer Res.</i> , 59:4906-4911, 1999.
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	C52	Klein <i>et al.</i> , "Locally advanced prostate cancer," <i>Curr. Treat. Options Oncol.</i> , 2:403-411, 2001.
	C53	Komatsu <i>et al.</i> , "Cre-loxP-mediated <i>bax</i> gene activation reduces growth rate and increases sensitivity to chemotherapeutic agents in human gastric cancer cells," <i>Cancer Gene Ther.</i> , 7:885-892, 2000.
	C54	Kraus <i>et al.</i> , "Alternative promoter usage and tissue specific expression of the mouse somatostatin receptor 2 gene," <i>FEBS LETT.</i> , 428:165-70, 1998.
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	C56	LaPointe <i>et al.</i> , "Upstream sequences confer atrial-specific expression on the human atrial natriuretic factor gene," <i>J. Biol. Chem.</i> , 263:9075-9078, 1988.
	C57	LaPointe <i>et al.</i> , "Use of a polymerase-chain-reaction-amplified DNA probe from <i>Pseudomonas putida</i> to detect D-hydantoinase-producing microorganisms by direct colony hybridization," <i>Appl. Microbiol. Biotechnol.</i> , 42:895-900, 1995.
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	C63	Meuleman and Mulders, "Erectile function after radical prostatectomy: a review," <i>Eur. Urol.</i> , 43:95-101, 2003.
	C64	Meyerson <i>et al.</i> , " <i>hEST2</i> , the putative human telomerase catalytic subunit gene, is up-regulated in tumor cells and during immortalization," <i>Cell</i> , 90:785-795, 1997.
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	C76	Paxton <i>et al.</i> , "Sequence analysis of carcinoembryonic antigen: identification of glycosylation sites and homology with the immunoglobulin supergene family," <i>Proc. Natl. Acad. Sci. USA</i> , 84:920-924, 1987.
	C77	Pound <i>et al.</i> , "Prostate-specific antigen after anatomic radical retropubic prostatectomy: patterns of recurrence and cancer control," <i>Urol. Clin. North Am.</i> , 24:395-406, 1997.
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U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

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Exam. Init.	Ref. Des.	Citation
	C86	Rubinchik <i>et al.</i> , "Enhanced apoptosis of glioma cell lines is achieved by co-delivering FasL-GFP and TRAIL with a complex Ad5 vector," <i>Cancer Gene Ther.</i> , 10:814-822, 2003.
	C87	Rubinchik <i>et al.</i> , In: <i>Virus Vectors for Gene Therapy: Methods and Protocols</i> , Humana Press, Inc., NJ, 2003.
	C88	Schrewe <i>et al.</i> , "Cloning of the complete gene for carcinoembryonic antigen: analysis of its promoter indicates a region conveying cell type-specific expression," <i>Mol. Cell. Biol.</i> , 10:2738-2748, 1990.
	C89	Schuur <i>et al.</i> , "Prostate-specific antigen expression is regulated by an upstream enhancer," <i>J. Biol. Chem.</i> , 271:7043-7051, 1996.
	C90	Seol <i>et al.</i> , "Adenovirus-TRAIL can overcome TRAIL resistance and induce a bystander effect," <i>Cancer Gene Ther.</i> , 10:540-548, 2003.
	C91	Shinoura <i>et al.</i> , "Adenovirus-mediated transfer of Bax with caspase-8 controlled by myelin basic protein promoter exerts an enhanced cytotoxic effect in gliomas," <i>Cancer Gene Ther.</i> , 7:739-748, 2000.
	C92	Shirakawa <i>et al.</i> , "Tissue-specific promoters in gene therapy for the treatment of prostate cancer," <i>Mol. Urol.</i> , 4:73-82, 2000.
	C93	Smith-Arica <i>et al.</i> , "Cell-type-specific and regulatable transgenesis in the adult brain: adenovirus-encoded combined transcriptional targeting and inducible transgene expression," <i>Mol. Ther.</i> , 2:579-587, 2000.
	C94	Smith-Arica <i>et al.</i> , "Switching on and off transgene expression within lactotrophic cells in the anterior pituitary gland <i>in vivo</i> ," <i>Endocrinol.</i> , 142:2521-2532, 2001.
	C95	Snoek <i>et al.</i> , "Differential transactivation by the androgen receptor in prostate cancer cells," <i>Prostate</i> , 36:256-263, 1998.
	C96	Spencer <i>et al.</i> , "Controlling signal transduction with synthetic ligands," <i>Science</i> , 262:1019-1024, 1993.
	C97	Takakura <i>et al.</i> , "Cloning of human telomerase catalytic subunit (hTERT) gene promoter and identification of proximal core promoter sequences essential for transcriptional activation in immortalized and cancer cells," <i>Cancer Res.</i> , 59:551-557, 1999.

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Form PTO-1449 (modified)		Atty. Docket No.: MESC:014US	Serial No.: 10/555,109
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	C98	Tang <i>et al.</i> , "Vigilant vectors: adeno-associated virus with a biosensor to switch on amplified therapeutic genes in specific tissues in life-threatening disease," <i>Methods</i> , 28:259-266, 2002.
	C99	Thompson <i>et al.</i> , "Carcinoembryonic antigen gene family: molecular biology and clinical perspectives," <i>J. Clin. Lab. Anal.</i> , 5:344-366, 1991.
	C100	Tsumaki <i>et al.</i> , "Modular arrangement of cartilage- and neural tissue-specific <i>cis</i> -elements in the mouse $\alpha 2$ (DI) collagen promoter," <i>J. Biol. Chem.</i> , 273:22861-22864, 1998.
	C101	van Beusechem <i>et al.</i> , "Conditionally replicative adenovirus expressing a targeting adapter molecule exhibits enhanced oncolytic potency on CAR-deficient tumors," <i>Gene Ther.</i> , 10:1982-1991, 2003.
	C102	Vigne <i>et al.</i> , "Genetic manipulations of adenovirus type 5 fiber resulting in liver tropism attenuation," <i>Gene Ther.</i> , 10:153-162, 2003.
	C103	Voelkel-Johnson <i>et al.</i> , "Resistance of prostate cancer cells to soluble TNF-related apoptosis-inducing ligand (TRAIL/Apo2L) can be overcome by doxorubicin or adenoviral delivery of full-length TRAIL," <i>Cancer Gene Ther.</i> , 9:164-172, 2002.
	C104	Volk <i>et al.</i> , "Enhanced adenovirus infection of melanoma cells by fiber-modification," <i>Cancer Biol. Ther.</i> , 2:511-515, 2003.
	C105	Wang <i>et al.</i> , "Ligand-inducible and liver-specific target gene expression in transgenic mice," <i>Nature Biotech.</i> , 15:239-243, 1997.
	C106	Wang, "A regulatory system for use in gene transfer," <i>Proc. Natl. Acad. Sci. USA</i> , 91:8180-8184, 1994.
	C107	Weinrich <i>et al.</i> , "Reconstitution of human telomerase with the template RNA component hTR and the catalytic protein subunit hTERT," <i>Nature Genet.</i> , 17:498-502, 1997.
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	C109	Wildner, "Comparison of replication-selective, oncolytic viruses for the treatment of human cancers," <i>Curr. Opin. Mol. Ther.</i> , 5:351-361, 2003.
	C110	Wu <i>et al.</i> , "Generation of a prostate epithelial cell-specific Cre transgenic mouse model for tissue-specific gene ablation," <i>Mech. Dev.</i> , 101:61-69, 2001.

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	C111	Wu <i>et al.</i> , "Promoter-dependent tissue-specific expressive nature of imprinting gene, insulin-like growth factor II, in human tissues," <i>Biochem. Biophys. Res. Commun.</i> , 233:221-226, 1997.
	C112	Wyborski and Short, "Analysis of inducers of the <i>E.coli lac</i> repressor system in mammalian cells and whole animals," <i>Nucleic Acids Res.</i> , 19:4647-4653, 1991.
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	C114	Yamamoto <i>et al.</i> , "Infectivity enhanced, cyclooxygenase-2 promoter-based conditionally replicative adenovirus for pancreatic cancer," <i>Gastroenterology</i> , 125:1203-1218, 2003.
	C115	Yamauchi-Takahara <i>et al.</i> , "Characterization of human cardiac myosin heavy chain genes," <i>Proc. Natl. Acad. Sci. USA</i> , 86:3504-3508, 1989.
	C116	Yazawa <i>et al.</i> , "Current progress in suicide gene therapy for cancer," <i>World J. Surg.</i> , 26:783-789, 2002.
	C117	Zhang <i>et al.</i> , "A small composite probasin promoter confers high levels of prostate-specific gene expression through regulation by androgens and glucocorticoids <i>in vitro</i> and <i>in vivo</i> ," <i>Endocrinology</i> , 141:4698-4710, 2000.
	C118	Zhao-Emonet <i>et al.</i> , "Deletional and mutational analyses of the human CD4 gene promoter: characterization of a minimal tissue-specific promoter," <i>Biochim. Biophys. Acta.</i> , 1442:109-119, 1998.
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